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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,048	12/22/2004	John Erik Hansen	1175/73653	6761

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EXAMINER	
HOFFMAN, SUSAN COE	
ART UNIT	PAPER NUMBER
1655	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/519,048	HANSEN, JOHN ERIK	
	Examiner	Art Unit	
	Susan Coe Hoffman	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-9 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-9 is/are rejected.

7)☒ Claim(s) 1-9 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 4/05.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The preliminary amendment filed December 22, 2004 has been received and entered.

2. Claims 1-9 are currently pending.

Specification

3. The abstract of the disclosure is objected to because the abstract is two paragraphs. Abstracts must be only one paragraph. Correction is required. See MPEP § 608.01(b).

Claim Objections

4. Claims 1-9 are objected to because of the following informalities: the independent claim should begin "A vitamin..." and the dependent claims should begin "The vitamin...". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claim 1 is indefinite because it is not clear what applicant considers "external" and "internal" immune responses. In addition, it is unclear how the stability of the immune

responses are measured and what would be considered a stabilized immune response. Furthermore, it is unclear what is meant by the kits being used "successively or separately."

6. Claims 2 and 3 are indefinite because the antecedent basis for "the carrier" is unclear. Claim 1 claims are carrier in both kit 1 and kit 2. It is unclear if the carrier claimed in claims 2 and 3 is referring to the carrier in kit 1, kit 2 or both kits. If the carrier is referring to the carrier in kit 1, the claims need to clarify that the claimed carriers are added to the carrier already claimed in kit 1.

7. Claims 4, 6, and 7 are indefinite because it is unclear what "the standard dosage" and the "ordinary prescribed dosage" is for each of the claimed ingredients.

8. Claims 5, 8, and 9 are indefinite because the use of parentheses makes it unclear if the enclosed limitations are a required part of the claim. Furthermore, it is unclear what other elements are encompassed by "etc.". In addition, it is unclear if the kits are intended to be directly applied to the areas of the body mentioned.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 5,973,224, US Pat. No. 6,190,685, and US Pat. No. 5,948,443.

US '224 teaches a composition comprising plant embryos such as oat, radish, barley, and vitamin E, vitamin C, biotin and selenium. The composition can be stabilized and ground to a powder. The composition is used for improving the immune system of immuno-compromised patients such as those with HIV (see columns 2-4). The reference does not specifically teach using bran; however, bran is a natural component of oats. Thus, bran would naturally be present in the composition of US '224.

US '685 teaches using allicin containing garlic oil to treat immune disease such as HIV (see column 7, lines 37-42 and column 11, line 42-column 12, line 10).

These references show that it was well known in the art at the time of the invention to use the claimed ingredients in compositions that treat HIV. It is well known that it is prima facie obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. In re Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); In re Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Based on the disclosure by these references that these substances are used in compositions to treat HIV, an artisan of ordinary skill would have a reasonable expectation that a combination of the substances would also be useful in creating compositions to treat HIV. Therefore, the artisan would have been motivated to combine the claimed ingredients into a single system for treatment. No patentable invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the

ingredients. See In re Sussman, 1943 C.D. 518; In re Huellmantel 139 USPQ 496; In re Crockett 126 USPQ 186.

The references together teach using all of the claimed ingredients together. The references do not specifically teach dividing up the ingredients into specific "kits." However, US '443 teaches that it was known in the art at the time of the invention that ingredients used together for treatment can also be divided up into different units (see column 6). The division of ingredients into different units would allow the artisan of ordinary skill for increased flexibility in administration of the claimed compositions. Thus, the artisan would be motivated to optimize the division of the ingredients in order to best achieve the results desired by the references.

The references also do not specifically teach adding the ingredients in the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

The references do not specifically teach the dosage and administration scheme claimed by applicant. However, these are considered intended use recitations that do not alter the basic

properties of the claimed compositions. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

10. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe Hoffman whose telephone number is (571) 272-0963. The examiner can normally be reached on Monday-Thursday, 9:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

1-23-07

Susan Coe Hoffman
Primary Examiner
Art Unit 1655